4164-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0025]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

**AGENCY:** Food and Drug Administration, Health and Human Services (HHS).

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to

https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0721. Also include the FDA docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** JonnaLynn Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-3794, PRAStaff@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Food Labeling; Declaration of Certified and Non-Certified Color Additives

OMB Control Number 0910-0721--Extension

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (FD&C Act) to issue regulations concerning animal food. Specifically, section 403(i) of the FD&C Act (21 U.S.C. 343(i)) requires that certified color additives used in or on a food must be declared by their common or usual names and not be designated by the collective term "colorings." Our regulations in part 501 (21 CFR part 501) set forth the requirements for animal food labeling. Under § 501.22(k)(21 CFR 501.22(k)), animal food manufacturers must declare on the animal food label the presence of certified and noncertified color additives in their animal food products. Our animal food labeling regulation at § 501.22(k) is consistent with the regulations requiring the declaration of color additives on human food labels. The purpose of the labeling is to provide animal owners with information on the color additives used in animal food. Animal owners use the information to become knowledgeable about the foods they purchase for their animals. Color additive information enables a consumer to comparison shop and to avoid substances to which their animals may be sensitive.

In the *Federal Register* of March 4, 2021 (86 FR 12690), FDA published a 60-day notice requesting public comment on the proposed collection of information. We received 22 comments expressing the importance of color additive information on pet food labeling, along with other ingredient disclosures. FDA appreciates these comments; at this time, we are not revising the regulations found at § 501.22(k) related to color additive information on the labeling of animal food.

FDA estimates the burden of this collection of information as follows:

Description of Respondents: Respondents to this collection of information are manufacturers of pet food products that contain color additives.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Third-Party Disclosure Burden<sup>1</sup>

21 CFR Section; Activity	No. of	No. of	Total	Average	Total
	Respondents	Disclosures per	Annual	Burden per	Hours
		Respondent	Disclosures	Disclosure	
501.22(k); labeling of color additive	3,120	0.8292	2,587	0.25	647
or lake of color additive; labeling of				(15 minutes).	
color additives not subject to					
certification					

<sup>&</sup>lt;sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: July 2, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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